MAR 2 3 2009

510(k) Summary

Submitted by: DePuy Orthopaedics, Inc.
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Contact Person: Suzana Otaño, Project Manager, Regulatory Affairs

Date Prepared: December 18, 2008

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
ACE-Fischer External Fixation System	Single/multiple component metallic bone fixation appliances and accessories

Name of Predicate Devices

The device is substantially equivalent to the currently marketed DePuy ACE-Fischer External Fixation system that consists of K801594: ACE-Fischer External Fixation System, K860014: Fischer Wire/Pin Clamp, K875012: ACE-Fischer Percutaneous Half Pins and K955388: ACE Dupont Composite Rings.

Classification

Class II, 21 CFR 888.3030 and 888.3040

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act for these devices.

Indications for Use

The updated **ACE-Fischer® External Fixation System** is indicated for open and closed long bone fracture fixation to include tensioned wire fixation of periarticular fractures, arthrodesis, limb lengthening, osteotomy, reconstruction, non-unions, pseudoarthrosis, correction of bony or soft tissue defects and deformities.

Device Description

The updated **ACE-Fischer® External Fixation System** is a highly versatile frame that can be constructed for applications ranging from simple fractures to complex reconstruction. This modular system can be configured for many different applications.

Biocompatibility

The updated **ACE-Fischer® External Fixation System** does not require biocompatibility testing.

Summary of Substantial Equivalence

The updated **ACE-Fischer® External Fixation System** is substantially equivalent to the predicate devices. Equivalence was confirmed through bench testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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DePuy Orthopaedics, Inc.
% Ms. Suzana Otaño
Project Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K083789
Trade/Device Name: ACE-Fischer External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulation Class: Class II
Product Code: KTT, JDW
Dated: February 18, 2009
Received: February 19, 2009

Dear Ms. Otaño:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K083789

Device Name: **ACE-Fischer® External Fixation System**

Indications For Use:

The updated **ACE-Fischer® External Fixation System** is indicated for open and closed long bone fracture fixation to include tensioned wire fixation of periarticular fractures, arthrodesis, limb lengthening, osteotomy, reconstruction, non-unions, pseudoarthrosis, correction of bony or soft tissue defects and deformities.

Prescription Use X AND/OR Over-the-Counter
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number